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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/271,891	3/19/99	CHERN	R 20023Y

000210
MERCK AND CO INC
P O BOX 2000
RAHWAY NJ 07065-0907

HM12/1219

EXAMINER	
SHARAREH,S	
ART UNIT	**PAPER NUMBER**
1619	14

DATE MAILED: 12/19/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.	Applicant(s)
09/271,098	Chern et al
Examiner	**Group Art Unit**
Shahnam Sharareh	1619

☒ Responsive to communication(s) filed on *Oct 2, 2000*

☒ This action is **FINAL.**

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire *3* month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claim

☒ Claim(s) *1-14* is/are pending in the applicat

Of the above, claim(s) _____ is/are withdrawn from consideration

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) *1-14* is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☒ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☒ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

DETAILED ACTION

The request filed on October 2, 1999 for Request Continued Examination (RCE) under 37 CFR 1.17(e) based on parent Application No. 09/271,098 is acceptable and a RCE has been established. An action on the RCE follows.

Status of Claims

Claims 1-14 are amended. Claims 1-14 are now pending

Response to Arguments

1. Applicant's amendment to claims 1-14 overcame the rejection made under 35 U.S.C. 112, second paragraph, said rejection is withdrawn.

2. Applicant's arguments with respect to the rejection made under 35 U.S.C. 102(e) as being anticipated by by Lewis US Patent 5,733,566 has been considered, and are found persuasive, because Lewis does not disclose a film coated or encapsulated liquid implant. Said rejection is withdrawn.

3. Applicant's arguments with respect to the rejection made under U.S.C. 103(a) as being unpatentable over Dunn et al US Patent 5,278,202, Yewey et al US Patent 5,780,044 and Lewis et al US Patent 5,733,566 has been considered, are found persuasive, because the cited arts do not disclose a film coated liquid implant. Said rejection is withdrawn.

4. Applicant's arguments with respect to the rejection of claims 1-14 under 35 U.S.C. 102(e) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Tipton et al US Patent 5,792,469 have been considered, but are not found persuasive.

Applicant argues that Tipton et al do not teach film encapsulated liquid implants. In response Examiner states that the instant claims are now directed to film coated liquid implant formed upon injection of a liquid composition comprising a hydrophobic bioactive substance, a poly(lactide-co-glycolide) copolymer, and a mixture of hydrophilic with lipophilic solvents, wherein said composition is effective to form a film encapsulated liquid at the implant site.

Tipton et al disclose liquid polymeric compositions comprising a hydrophobic bioactive substance such as fibroblast growth hormones, various antibacterial and antiparasitic agents, *col 9*. Tipton et al also disclose suitable biocompatible polymers and copolymers such as polylactides and poly glycolides copolymers, *col 5 lines 8-24, claim 4*. In their examples, Tipton et al disclose the use of mixture hydrophilic and lipophilic solvent system comprising 5% of an equimolar mixture of sodium carbonate and citric acid, and about 60% N-methyl pyrrolidone, with about 3.5% of a 50/50 poly(lactide-co-glycolide) copolymers to form a thick film in situ, *col 13 lines 60-67*. Furthermore, Tipton et al the use of mixture solvent system to modulate the coagulation rate of the polymers as desired, *col 6 lines 49-59*. As discussed in Paper No. 9 it is Examiner's position that a gelatinous matrix as recognized by U.S.P. comprise a liquid matrix within, therefore, Tipton et al meet the limitations set forth in the instant claims.

Further, the recitation of claim 14 indicates that the final composition does not require any hydrophilic solvent, thus the solvent system is directed to purely a lipophilic solvent. Tipton et al disclose such solvent systems.

Furthermore, although Tipton et al do not fully disclose a solvent mixture comprising a hydrophilic and lipophilic solvents, they indicate that their solvent system preferably has an HLB value between 9 to 13 which is known in the art to make an oil in water solvent system, therefore, one ordinary skilled in the art would have been motivated to make Tipton's composition in a solvent mixture of choice because selecting the suitable solvent mixture for delivery of a specific lipophilic or hydrophilic agent is well known in the art as described by Tipton et al, and one of ordinary skill in the art would have had a reasonable expectation to succeed in improving the delivery of a therapeutic compound of choice by modifying the degree of lipophilcity or hydrophilicity of the solvent system.

New Grounds of Rejection

Double Patenting

5. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ormum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321© may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

6. Claims 1-14 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 1-29 of U.S. Patent No. 6,136,838. Although the conflicting claims are not identical, they are not patentably distinct from each other because they are directed to injectable polymeric compositions comprising 1%-30% of an active compound, a 1-20% of a biodegradable poly (lactide/glycolide)copolymer, and a hydrophilic/lipophilic solvent system that forms a liquid encapsulated implant.

Conclusion

7. No claims were allowed. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,

however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shahnam Sharareh, PharmD whose telephone number is (703) 306-5400. The examiner can normally be reached on Monday to Friday from 8:30 a.m. to 5:00 p.m. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mr. Jose Dees can be reached on 703-308-4628. The fax phone number for this Group is 703-308-4556. Any inquiry of a general nature of relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is 703-308-1235.

sjs,12/10/2000

DIANA DUDASH
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600